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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,975	10/01/2002	Manfred Schawaller	MBP-009 XX	6238

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EXAMINER	
CHIN, CHRISTOPHER L	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,975	SCHAWALLER ET AL.	
	Examiner	Art Unit	
	Christopher L. Chin	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 27-55* is/are pending in the application.

4a) Of the above claim(s) *38-44 and 48-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,27-37,45-47 and 52-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-6 and 27-55* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/19/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I – claims 1-6, 27-37, 45-47, and 52-55 in the reply filed on 12/21/05 is acknowledged. The traversal is on the ground(s) that the examiner has misinterpreted the teachings of the '879 patent and the '879 patent suffers from a number of disadvantages. This is not found persuasive because the examiner has not misinterpreted the '879 patent. The '879 patent was relied upon to teach the microtiter plate and kit arrangement of Group II, which was determined to be the special technical feature that linked the invention together. Since the '879 patent discloses the microtiter plate and kit, there is no longer any special technical feature that links all three groups together into a single inventive concept. The disadvantages of the '879 patent have been noted but are not seen to be relevant in determining whether or not the '879 discloses the special technical feature.

The requirement is still deemed proper and is therefore made FINAL.

Claims 38-44 and 48-51 are withdrawn from consideration.

Claim Rejections - 35 USC § 112

2. Claims 1-6, 27-37, 45-47, and 52-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification, as originally filed, is not enabled for the method of claim 1. The assay method of claim 1 relies on detection of a fluorophor that is part of a complex that includes the substance that is being assayed for and a reaction partner R1 that is bonded to a surface. Bound fluorophor is excited by an evanescent field generated near the surface. Once excited, a fluorescent signal is detected to signal the presence of bound substance. The claimed method also recites the use of at least one dye that absorbs in the absorption and/or emission range of the fluorphor. The dye essentially quenches the fluorescence emitted by the fluorophor since it absorbs in the same absorption and/or emission range of the fluorophor. The claimed method fails to recite any means for preventing the dye from coming into contact or be near fluorophore in the complex at the surface. The presence of dye near the surface would quench the fluorescent signal from bound fluorophor and thus prevent detection of bound substance.

3. Claims 1-6, 27-37, 45-47, and 52-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague because it is not clear as to how "a complex forms on reaction partner R1" comprising R1, the substance being assayed, and the compound containing at least one fluorophore. The claim fails to recite any relationship between these reagents, essentially what is binding to what. The claim is also not clear with respect to the function of the dye in assaying for the substance or whether it is contacted with the

complex that is formed. In the last part of the claim, the recitation of "the evanescence field" lacks antecedent support and is not clear as to how a light source can produce an evanescence field by itself to excite any fluorophore bonded to the surface. An evanescence field is normally generated at a surface of a waveguide when light is totally internally reflected within the waveguide. Thus, a light source cannot, by itself, generate an evanescence field as suggested by the claim. The claim is also incomplete because it lacks a correlation step that relates the measured fluorescence to the presence of the substance that is being assayed for. The claim is vague with respect to the "at least one compound containing a fluorophore" because it is not clear as to what comprises this compound aside from the fluorophore. The claim is vague with respect to how the dye is kept away from the fluorophore that becomes complexed to R1 on the surface. The fluorophore appears to be how the presence of substance complexed to R1 is detected. If the dye is allowed near the surface, any fluorescence from the fluorophore will be absorbed by the dye and the presence of the fluorophore will not be detected, which means the substance will also not be detected.

Claim 2 is vague because it stipulates that R2 is bonded on the surface while claim 1 stipulates that R1 is bonded to the surface.

Claim 4 is vague because it is not clear with respect to the function of R2. The claim is also vague with respect to what comprises R2 aside from the substance being assayed for.

Claim 27 is vague because it recites improper Markush language. The phrase "selected from the group of" should be amended to read – selected from the group consisting of --.

Claim 28 is vague. The recitation of "includes a protein" is not clear if the substance being assayed for is a protein or contains a protein. If it contains a protein, then the claim is also not clear as to what else comprises the substance. The recitation of "preferably" is also vague because it is not clear if an antigen or antibody is meant to be limiting or not.

Claim 31 is vague because it appears to recite trademark compounds (Cryptofluor Crimson and Cryptofluor Red) without defining them with generic terminology. The composition of trademark compounds are subject to change while their trademark names can stay the same. The claim is further vague in reciting the phrase "such as" because it is not clear as to whether the allophycocyanine is meant to be exemplary or limiting.

Claim 32 is vague because it appears to recite trademark compounds (Cy5 and BODIFY) without defining them with generic terminology. The composition of trademark compounds are subject to change while their trademark names can stay the same.

Claim 37 is vague because it appears to recite trademark compounds (Brilliant Blue FCF) without defining them with generic terminology. The composition of trademark compounds are subject to change while their trademark names can stay the same.

Claim 47 is vague. The recitation of "includes a protein" is not clear if the substance being assayed for is a protein or contains a protein. If it contains a protein, then the claim is also not clear as to what else comprises the substance. The recitation of "preferably" is also vague because it is not clear if an antigen or antibody is meant to be limiting or not. The claim is further vague because it appears to recite trademark compounds (Cryptofluor Crimson, Cryptofluor Red, Cy5, BODIFY, and Brilliant Blue FCF) without defining them with generic terminology. The composition of trademark compounds are subject to change while their trademark names can stay the same. The claim is further vague in reciting the phrase "such as" because it is not clear as to whether the allophycocyanine is meant to be exemplary or limiting.

4. Claims 45, 46, 52, and 54 provides for the use of a method of assay, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 45, 46, 52, and 54 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher L. Chin whose telephone number is (571) 272-0815. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher L. Chin
Primary Examiner
Art Unit 1641

3/6/06